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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,398	07/18/2003	Elizabeth M. Denholm	IT 105 CON	4646

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,398	DENHOLM ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-11* is/are pending in the application.

4a) Of the above claim(s) *9 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-8, 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 9 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species. Election was made **without** traverse in the reply filed on 3/9/2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4-8, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/01648 (abstract, page 1, lines 20-30, page 3, lines 25-end, page 4, lines 1-10, page 29, lines 5-15, page 32, lines 20-30, page 56, lines 5-end, page 57, lines 1-10).

WO teaches that chondroitinases AC and B are well known to be from *Flavobacterium heparinium* and are known to be used to manipulate cell proliferation. Treating a wound would encompass reducing cell proliferative response and decreasing fibroblast proliferation. WO teaches that an individual is treated after a wound (page 32, lines 20-30) and such a wound would have scarring. In fact, WO teaches that wound healing in the patients treated were even evaluated for the types of scabs that were formed which would clearly have scarring, see page 56, line 25-page 57, line 10. It is also noted that the enzymes can be administered locally, see page 29, lines 5-15.

Claims 1, 4, 6, 7, 8, 10 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Sasisekharan et al. '417 (abstract, col. 4, lines 30-40, col. 15, line 60-col.

16, line 20), WO 95/13830 (abstract, page 11, lines 25-30, the claims), or Sasisekharan et al. '430 (paragraphs 31, 63, 109, 145).

Each reference teaches that a heparinase 1, 2 or 3 from Flavobacterium heparium is administered locally to treat psoriasis. Someone with psoriasis would develop scars. Treating psoriasis is trying to reduce cell proliferative response since the who point of treating psoriasis is to stop the over production of cells which leads to the psoriasis. This treating of psoriasis would also decrease fibroblast proliferation.

Claims 1, 2, 4-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Yacoby-Zeevi (col. 5, lines 23-35, col. 6, lines 1-15, 55-65, col. 12, lines 40-55, the claims).

The reference teaches that a heparinase 1, 2 or 3 from Flavobacterium heparium is administered to treat pulmonary fibrosis. Other diseases such as cystic fibrosis, pulmonary emphysema, asthma, etc. The reference clearly treats these diseases with the enzyme which would reduce cellproliferative response since this is what manifests the diseases. Clearly, treating these diseases with the enzymes also will decrease fibroblast proliferation as well. These are all diseases where such responses are inherent as noted by applicants in their own specification. The reference also uses chondroitinases ABC, AC, B, and C to treat such diseases.

Claims 1, 6, 7, 8, 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Heinrikson et al. (col. 14, lines 25-40, example 1).

Heinrikson teaches topically administering heparanase to treat psoriasis. See also above explanations regarding psoriasis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yacoby-Zeevi (col. 5, lines 23-35, col. 6, lines 1-15, 55-65, col. 12, lines 40-55, the claims) in view of Sasisekharan et al. '417 (abstract, col. 4, lines 30-40, col. 15, line 60-col. 16, line 20), WO 95/13830 (abstract, page 11, lines 25-30, the claims), or Sasisekharan et al. '430 (paragraphs 31, 63, 109, 145).

The reference teaches that a heparinase 1, 2 or 3 from Flavobacterium heparium is administered to treat pulmonary fibrosis. It also teaches treating diseases that have angiogenesis as a pathological consequence such as cystic fibrosis, pulmonary emphysema, asthma, etc. The reference also uses chondroitinases to treat such diseases.

What Yacoby does not teach is that the enzymes are administered locally.

The Sasisekharan references and the WO teach that a heparinase 1, 2 or 3 from Flavobacterium heparium are administered locally to treat psoriasis.

Thus since one would know to treat psoriasis locally with heparinase then one would have been motivated to treat another disease that has angiogenesis as a pathological consequence such as pulmonary emphasema locally also with a heparinase. Thus, to treat the emphasema should not be only restricted to inhalation but can also be administered locally according to the secondary references.

Claims 1, 2, 4-8, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrikson et al. (col. 14, lines 25-40, example 1) taken with WO 96/01648 (abstract, page 1, lines 20-30, page 3, lines 25-end, page 4, lines 1-10, page 29, lines 5-15, page 32, lines 20-30, page 56, lines 5-end, page 57, lines 1-10).

Heinrikson teaches topically administering heparanase to treat psoriasis.

Heinrikson does not teach that the enzymes come from the claimed microorganism.

WO teaches that chondroitinases AC and B are well known to be from *Flavobacterium heparinium* and are known to be used to manipulate cell proliferation. Treating a wound would encompass reducing cell proliferative response and decreasing fibroblast proliferation. WO teaches that an individual is treated after a wound (page 32, lines 20-30) and such a wound would have scarring. In fact, WO teaches that wound healing in the patients treated were even evaluated for the types of scabs that were formed which would clearly have scarring, see page 56, line 25-page 57, line 10. It is also noted that the enzymes can be administered locally, see page 29, lines 5-15.

Since WO each teach that chondroitinase B from Flavobacterium heparium is known to be administered locally to manipulate cell proliferation then it would have been obvious to use chondroitinases from Flavobacterium heparium instead of the heparinase since WO shows that chondroitinases from Flavobacterium heparium achieve beneficial results in manipulating cell proliferation which is important in treat psoriasis since one would want to manipulate the cell proliferation to reduce the rate to control the psoriasis. One would also be motivated to use bacterial enzymes since WO

clearly shows that such enzymes are well known and very beneficial which comes from microorganisms.

Claims 1, 2, 4-8, 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Sasisekharan et al. '417 (abstract, col. 4, lines 30-40, col. 15, line 60-col. 16, line 20), WO 95/13830 (abstract, page 11, lines 25-30, the claims), or Sasisekharan et al. '430 (paragraphs 31, 63, 109, 145) taken with WO 96/01648 (abstract, page 1, lines 20-30, page 3, lines 25-end, page 4, lines 1-10, page 29, lines 5-15, page 32, lines 20-30, page 56, lines 5-end, page 57, lines 1-10).

The primary references teach that a heparinase 1, 2 or 3 from Flavobacterium heparium is administered locally to treat psoriasis.

The primary references do not teach treating psoriasis with a chondroitinase.

WO teaches that chondroitinases AC and B are well known to be from *Flavobacterium heparinium* and are known to be used to manipulate cell proliferation. WO teaches that an individual is treated after a wound (page 32, lines 20-30) and such a wound would have scarring. In fact, WO teaches that wound healing in the patients treated were even evaluated for the types of scabs that were formed which would clearly have scarring, see page 56, line 25-page 57, line 10. It is also noted that the enzymes can be administered locally, see page 29, lines 5-15.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655

MVM